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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,639	11/20/2000	Didier Colavizza	C1190/20006	8287

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EXAMINER	
LAMBERTSON, DAVID A	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/716,639	COLAVIZZA ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-22,25-29,31-35 and 37-65* is/are pending in the application.

4a) Of the above claim(s) *20-22 and 25* is/are withdrawn from consideration.

5)☒ Claim(s) *38,40,41,43,44 and 46* is/are allowed.

6)☒ Claim(s) *26-29,31-35,37,39,42,45 and 47-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 27, 2004 has been entered.

Claims 20-22, 25-29, 31-35 and 37-65 are pending in the instant application. Claims 20-22 and 25 are withdrawn from further consideration as being drawn to a non-elected invention. Claims 26-29, 31-35 and 37-65 are under examination in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 27, 29, 32-35, 37, 39, 42, 45, 47-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that strains CNCM I-2412 and CNCM I-2422 are required to practice the invention. As such, the strains must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or

available, a deposit of the strain may satisfy the requirements of 35 U.S.C. 112, first paragraph.

In the instant case, the processes to generate strains that are disclosed in the specification does not appear to be repeatable, nor does it appear the strain is readily available to the public.

> If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;

d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

e) the deposit will be replaced if it should ever become inviable.

Failure to make one of the preceding indications in response to this Office Action will result in the rejection being maintained in either a second Non-Final or a Final rejection.

It is noted that in Applicant's response filed September 3, 2003, a statement regarding the deposit of strains was submitted. However, that statement only reflected the deposit of strain CNCM I-2421 and Applicant's agreement to satisfy the deposit rules regarding that particular strain. No statement regarding meeting the deposit rules was made regarding strains CNCM I-2412 or CNCM I-2422. As such, the deposit requirements for claims reciting the use of CNCM

I-2412 and CNCM I-2422 have not been met, and the deposit rejection regarding those claims is reinstituted.

Claims 26-29, 31, 32, 34, 35, 37, 47-51 and 53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a baker's yeast composition "obtainable by" the cultivation of strains selected from the group consisting of CNCM I-2421, CNCM 2422 and a *PAD1* deletion strain. The claims read on a broad genus of baker's yeast compositions that are "obtained by" the cultivation of the aforementioned strains, but that can presumably be obtained by cultivation of other strains.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims a baker's yeast product that is "obtainable by" cultivating three particular yeast strains, without any disclosed or known correlation between the starting strains

and their function in the composition (i.e., that has a gas production of at least 150 ml in two hours in test A1, gas production of at least 90 ml in two hours in test A5, gas production of at least 80 ml in two hours in test A6, a resistance to freeze-stress, and a lack of production of "bad taste and off-flavors" in the presence of cinnamon). Thus, it is unclear whether or not those strains must be a component of the claimed baker's yeast composition, or if the baker's yeast composition can be "obtained by" cultivating different yeast strains. The specification only provides teachings regarding the cultivation of I-2421, I-2422 and *PAD1* deletion strains to manufacture baker's yeast compositions having the required properties. The specification does not teach what other starting yeast strains can be used to produce the claimed baker's yeast compositions. In other words, the skilled artisan cannot envision what starting yeast strains possess a structure (i.e., a specific genetic make-up) that necessarily will produce a baker's yeast composition that possesses the function of producing at least 150 ml of gas in two hours in test A1, producing at least 90 ml of gas in two hours in test A5, producing at least 80 ml of gas in two hours in test A6, a resistance to freeze-stress, and a lack of production of "bad taste and off-flavors" in the presence of cinnamon The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only discloses baker's yeast compositions manufactured by the cultivation of the I-2421, I-2422 and *PAD1* deletion strains.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a representative number of yeast strains (other than CNCM I-2421, CNCM I-2422 and strains deleted for the PAD1 gene) that can be cultivated to produce a baker's yeast composition

having the required properties, so that one of skill in the art could envision the claimed invention. Thus the skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Because neither the instant specification nor the prior art teaches the full scope of yeast strains that can be cultivated to produce the claimed baker's yeast compositions, the skilled artisan would not be able to envision the claimed invention. Therefore, Applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claims 26-29, 31, 32, 34, 35, 37, 47-51 and 53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a baker's yeast composition having a gas production of at least 150 ml in two hours in test A1, gas production of at least 90 ml in two hours in test A5, gas production of at least 80 ml in two hours in test A6, a resistance to freeze-stress, and a lack of production of "bad taste and off-flavors" in the presence of cinnamon obtained by the cultivation of the I-2421, I-2422 or *PAD1* deletion strain, does not reasonably provide enablement for a baker's yeast composition (having the specifically indicated functional properties) "obtainable by" the cultivation of any other yeast strains. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art

without undue experimentation (*United States v. Telectronics*., 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The claimed invention is a baker's yeast composition "obtainable by" the cultivation of strains selected from the group consisting of CNCM I-2421, CNCM 2422 and a *PAD1* deletion strain. The claims read on a broad genus of baker's yeast compositions that are "obtainable by" the cultivation of the aforementioned strains, but are also "obtainable by" cultivation of other strains; this is because the term "obtainable by" does not distinctly limit the claimed composition to being *obtained from* the specific strains listed. It is noted, however, that the baker's yeast composition must necessarily have various properties, including specific performance results in A1, A5 and A6 fermentometer tests (gas production of at least 150 ml in two hours, gas production of at least 90 ml in two hours, and gas production of at least 80 ml in two hours, respectively), a resistance to freeze-stress, and a lack of production of "bad taste and off-flavors" in the presence of cinnamon. Thus, in order to make the claimed invention, the skilled artisan must know the full breadth of strains that will necessarily result in the production of a baker's yeast composition that has all of those properties when they are cultivated.

Breadth of the claims. The claims are very broad, indicating that the claimed baker's yeast composition is "obtainable by" cultivating virtually any starting yeast strain, so long as those strains give rise to the specific properties listed above in the Nature of the Invention.

Number of working examples and Guidance provided by applicant. The instant specification provides three examples of strains that give rise to baker's yeast compositions having a gas production of at least 150 ml in two hours in test A1, gas production of at least 90 ml in two hours in test A5, gas production of at least 80 ml in two hours in test A6, a resistance to freeze-stress, and a lack of production of "bad taste and off-flavors" in the presence of cinnamon: CNCM I-2421, CNCM I-2422 and strains deleted for the *PAD1* gene. There is no indication in the specification of what other strains will give rise to a baker's yeast composition that will have these specific properties when they are cultivated. Thus, the skilled artisan would need to consult the state of the art in hopes of determining what other yeast strains can be cultivated to obtain the claimed baker's yeast compositions.

State of the art. The state of the art is silent regarding other strains that can be used to obtain the claimed baker's yeast composition. Thus, the skilled artisan would not be apprised of the full scope of the baker's yeast compositions that are claimed, there being no way to determine the strains that can be used to make the claimed invention.

Unpredictability of the art and Amount of experimentation required. The full scope of the invention is entirely unpredictable because the scope is not limited to obtaining the baker's yeast compositions from the three specific strains that are demonstrated to give rise to baker's yeast compositions having a gas production of at least 150 ml in two hours in test A1, gas production of at least 90 ml in two hours in test A5, gas production of at least 80 ml in two hours in test A6, a resistance to freeze-stress, and a lack of production of "bad taste and off-flavors" in the presence of cinnamon. In essence, the skilled artisan would be required to randomly and empirically determine what known yeast strains can give rise to baker's yeast compositions

having the desired properties, and also to generate any unknown strains that will also give rise to baker's yeast compositions having the desired properties. This requires a tremendous amount of undue (because it requires the testing of virtually limitless numbers of yeast strains) and unpredictable (because there is no way to ascertain which strains will and will not give rise to the desired properties) trial and error experimentation, rising to the level of having the skilled artisan perform an inventive step; this is because the skilled artisan must discover what is not unknown in both the art and the instant specification. As such, the instant specification is not enabling for the full scope of baker's yeast that are "obtainable by" the cultivation of NCM I-2421, CNCM I-2422 and strains deleted for the *PAD1* gene because it is unclear what other strains the claimed baker's yeast compositions are obtainable from.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-29, 31, 32, 34, 35, 37, 47-53 and 55-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26-29, 31, 32, 34, 35, 37, 47-51 and 53 are rejected for containing the phrase "obtainable by" in reference to the claimed baker's yeast. Specifically, the claims indicate that the baker's yeast composition is obtainable by cultivating a strain selected from I-2412, I-2422 or a strain deleted for the PAD1 gene. This is indefinite because it is unclear if there are other ways for obtaining the claimed baker's yeast composition, and what those other methods are. See also the rejections under 35 USC 112, first paragraph. It would be remedial to indicate that

the claimed baker's yeast is "*obtained by* a cultivation process comprising culturing a starting yeast strain selected from the group consisting of..."

Claims 27, 47, 48, 56, 60 and 61 are rejected for containing the phrase "wherein said gas release...by a process for manufacturing said control yeast, by cultivating...I-2412." In this phrase, it is unclear if I-2412 is serving as the control yeast strain, or if the baker's yeast composition is obtained by cultivating I-2412. It would be remedial to insert "wherein the control yeast is obtained" between the comma and the phrase "by cultivating."

Claims 26, 27, 32, 34, 35, 37, 47-53 and 55-65 are rejected for containing the phrase "bad taste and off-flavors." **This rejection is maintained for the reasons set forth in the previous Office Action, and is now applied to new claims 55-65.**

Response to Arguments Concerning Claim Rejections - 35 USC § 112

Applicant's arguments filed December 27, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal:

1. Applicant argues that "bad taste and off-flavors" can be determined by a jury, and are caused by the decomposition of cinnamic acid. Applicant additionally argues that the presence of cinnamic acid can be determined by chromatographic methods (see for example the first paragraph of page 22 of Applicant's Remarks). Notes given by a jury can be confirmed by these chromatographic methods to determine what level of cinnamic acid decomposition is equivalent to having a "bad taste and off-flavor" (see for example the second paragraph of page 23 of Applicant's response).

Applicant's traversal is not persuasive for the following reasons:

1. It is again asserted that the reliance on the opinion of a panel of jurists is a subjective test, and that a subjective test is in itself indefinite because it will change depending on the individuals present on a panel. Furthermore, although the presence of cinnamic acid can be determined by chromatographic methods and compared against the notes of a jury, neither the claim nor the specification clearly indicates what chromatographic results necessarily indicate that a "bad taste or off-flavor" is present. Thus, the test remains subjective, based upon the opinion of a particular panel of jurists. In the absence of definitive levels of cinnamic acid that result in the presence or absence of "bad taste or off-flavors," it remains indefinite as to what represents a "bad taste or off-flavor."

Allowable Subject Matter

Claims 38, 40, 41, 43, 44 and 46 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
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JAMES KETTER
PRIMARY EXAMINER